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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,775	09/12/2003	Raymond J.H. Westheim	SYN-0032	5762

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EXAMINER

SHIAO, REI TSANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/660,775

Applicant(s)

WESTHEIM, RAYMOND J.H.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 05/04, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 23-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the provisional application:
60/413,765 with a filing date 09/27/2002; and
60/470,223 with a filing date 05/14/2003.
2. Applicant's remarks/arguments filed on November 21, 2005, is acknowledged.
Claims 1-29 are pending in the application.

Responses to Arguments

3. Applicant's arguments regarding rejection of claims 1-22 under 35 U.S.C. 112, first paragraph, filed on November 21, 2005, have been fully considered and they are persuasive. Therefore, rejection of claims 1-22 under 35 U.S.C. 112, first paragraph, has been withdrawn herein.
4. Since the fully X-ray diffractogram data has not been incorporated into claims 3, 8, and 11, therefore, rejection of claims 3, 8, and 11 under 35 U.S.C. 112, second paragraph, is maintained. It is noted that the fully X-ray diffractogram data (i.e., Fig. 2) are distinct fingerprint characteristics of the instant polymorph form II. Moreover, claims 1 and 12, drawn to a crystalline bicalutamide of form II or amorphous form, does not have the fully distinct X-ray diffractogram data. Therefore, claims 1 and 12 are also rejected along with claims 3, 8 and 11 under 35 U.S.C. 112, second paragraph. It is suggested that incorporation of instant full and/or X-ray diffractogram data or IR absorbance data (i.e., Fig. 4) into claims 1, 3, 8, or 12 respectively, would obviate the rejection.

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5. Applicant's arguments regarding rejection of claims 1-11 and 14-22 under 35 U.S.C. 102(a) or 103(a) over Ekwuribe's US 6,583,306, have been fully considered but they are not persuasive. It is noted that Ekwuribe's '306 disclose the same instant compound N-(4-cyano-3-trifluoromethyl-phenyl)-3-(4-fluoro-phenylsulfonyl)2-hydroxy-2-methyl-propionamide (i.e., bicalutamide) in white crystal form, which clearly anticipate instant crystalline bicalutamide compound. Further, changing the form, purity or other characteristic (i.e., crystal form II) of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art, see *In re Cofer*, 148 U.S.P.Q. 268 (CCPA 1966). Moreover, Something which is old does not become patentable upon the discovery of a new property, see M.P.E.P. 2112. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA1977). Therefore, rejection of claims 1-11 and 14-22 under 35 U.S.C. 102(a) or 103 (a) over Ekwuribe's US 6,583,306, is maintained.

6. Applicant's arguments regarding rejection of claims 13-22 under 35 U.S.C. 102(b) or 103(a) over Tucker's US 4,636,505, have been fully considered but they are not persuasive. It is noted that Tucker's 505 disclose same compositions comprising the same instant compound bicalutamide. It is well recognized in the art that process of preparing pharmaceutical composition will produce the thermodynamically stable form of crystals, thus, Tucker's crystal form and instant form II, after mixing, grinding, compressing would both be transformed into the same thermodynamically

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stable form(s) of the instant claimed compound, also see Brittain's publication, polymorphism in Pharmaceutical Solids, Drugs and the Pharmaceutical Science; 1999, V. 95, pages 348-361. To demonstrate unobviousness from Tucker's compositions, applicants must show unexpected result stemming from the instant crystalline form over the crystalline form of Tucker's in form of distinct form(s) or mechanical advantage(s) of the instant crystal over the crystal of Tucker's, see Ex parte Conn and Norman, 119 USPQ 388 (1956), also see In re Grose & Flanigen, 201 USPQ57. Rejection of claims 13-22 under 35 U.S.C. 102(b) or 103(a) over Tucker's US 4,636,505, is maintained.

7. Applicant's arguments regarding provisional rejection of 13-22 under the judicially created doctrine of obviousness-type double patenting over claim 1 or 11 of Ortega et al. co-pending application No. 10/842,632, see US 2005/000,869 A1, have been fully considered but they are not persuasive. It is noted that Ortega et al. granule of formulation or compositions comprise the instant compound bicalutamide (i.e., at least 50%) and one pharmaceutically acceptable excipient, which is obvious to the instant claimed compositions or formulation, which comprise a compound bicalutamide and a pharmaceutically acceptable excipient. It is noted that Ortega et al. silence the instant crystal form for preparing the compositions. However, the applicable rule for interpreting the claims is that "each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description.", see MPEP 2163 (II)(1), citing In re Morris, 127 F. 3d 1048, 1053-1054; 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In view of this rule, Ortega et al. claims 1 or

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11 will be read to a composition comprising various amount (i.e., at least 50 %) of bicalutamide compound (i.e., in crystal form II) and a pharmaceutically acceptable excipient. To demonstrate unobviousness from Ortega et al. compositions, applicants must show instant crystalline form II is not used in Ortega et al. compositions.

Alternatively, unexpected results must be shown from stemming from the mechanical advantage(s) of the instant compositions over the Ortega et al. compositions.

Otherwise, a terminal disclaimer is requested to file to the Office.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

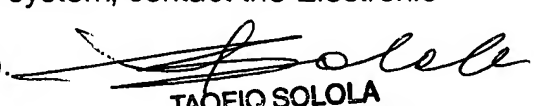
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Telephone Inquiry

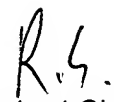
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


TAOFIQ SOLOLA
PRIMARY EXAMINER

 Joseph K. McKane
Supervisory Patent Examiner
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Robert Shiao, Ph.D.
Patent Examiner
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January 25, 2006